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BTS0001-100 (20446-002001)

U.S. App. No. 10/659,083

Filed September 9, 2003



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Examiner:

Simon Delagrave

Amber Steele

Serial No.: 10/659,083

Group Art Unit: 1639

Filed: **September 9, 2003**

Confirmation No.: 2730

For: **METHODS OF PREPARING IMPROVED AGENTS BY COEVOLUTION**

Mail Stop: Amendment
Commissioner of Patents
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RESPONSE TO RESTRICTION REQUIREMENT

This is in response to the Office Action dated March 22, 2006, in connection with the above captioned patent application.

The Examiner has required restriction to one of the following 13 Groups:

- I. Claims 1-12, drawn to a method of countering the development of resistance or neutralizing activity;
- II. Claims 13-25, drawn to a method of preparing an agent;
- III. Claims 26-27, drawn to a method of in vitro coevolving;
- IV. Claims 28-29, drawn to a method of coevolving;
- V. Claim 30, drawn to a method of producing a collection of evolved targets and a collection of evolved neutralizing agents;
- VI. Claims 31-33, drawn to a method of treating a disease;
- VII. Claims 34-35, drawn to a method of developing a desired characteristic in a parent antibody or parent target;
- VIII. Claims 36-37, drawn to a method of preparing an antibody;

- IX. Claims 38-39, drawn to an antibody;
- X. Claims 40-42, drawn to a method of treating a disease with an antibody;
- XI. Claim 43, drawn to a method of preparing an antigen;
- XII. Claims 44-45, drawn to an antigen
- XIII. Claim 46-50, drawn to a method of treating a disease with an antigen.

Applicant traverses the restriction requirement. For a restriction requirement to be valid, the Examiner must establish the following two criteria: (1) the existence of independent and distinct inventions, (35 U.S.C. 121); and (2) that the search and examination of the entire application cannot be made without serious burden (M.P.E.P. 803). Here, neither of the two criteria are established.

The Office Action fails to point to sufficient evidence showing that the Groups are distinct. For example, the Office Action incorrectly alleges that the Groups have different modes of operation, function, and/or effect because, for example, Group V requires “selecting one or more resistant targets” which no other Group requires. While the other Groups may not recite this “selecting” step verbatim, they pertain to a method of “coevolving” which, as set out in the specification at, for example, page 13, is carried out by successive “diversifying” and “selecting” steps. Accordingly, the “selecting” step is generally present anytime there is a “coevolving” step and is thus present in numerous Groups in addition to Group V.

The Office Action further fails to show that there would be a serious burden to conduct a proper search on the entirety of the claimed invention. A search of either Group I or Group II would inevitably require the searching of subject matter common to all the Groups because all the Groups are directed to aspects of in vitro coevolving. Accordingly, the subject matter of Groups I-XIII can be examined in a single application, resulting in economies to the Patent Office as well as the Applicant.

In order to advance prosecution, Applicant provisionally elects Group I, with traverse, but respectfully requests that the Examiner consider rejoining the other Groups, particularly Group II, for the reasons given above.

The Office Action further requires election of species. It is Applicant’s understanding that election of species is provisional, and that should the Examiner find no prior art that renders

the species anticipated or obvious, the search will be extended to non-elected species to the extent necessary to determine patentability of the claim. (See, e.g., M.P.E.P. 803.02).

Applicant hereby provisionally elects a species where:

a) the method is for countering the development of resistance in a parent target to a parent neutralizing agent;

b) the parent target is an antigen;

c) the parent neutralizing agent is a protein; and

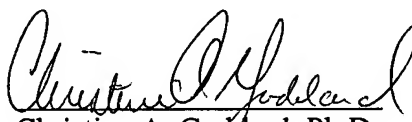
d) the outcome is a desired neutralization profile.

The Office Action further requests an election of a “species of diversifying” (if Group I is elected), however since “diversifying” relates to the parent neutralizing agent and parent target, and these have been elected as above, the “species of diversifying” is thus necessarily already elected.

Claims that read on the above election include 1-7 and 9-12. For the reasons provided above, reconsideration of this requirement is respectfully requested.

Applicant also notes submission of an Information Disclosure Statement together with this Response.

Respectfully submitted,



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